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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/IB95/01114 (22) International Filing Date: 11 December 1995 (11.12.95) (30) Priority Data: 08/381,788 31 January 1995 (31.01.95) US (71) Applicant: HOWMEDICA INC. [US/US]; 235 East 42nd Street, New York, NY 10017 (US). (72) Inventor: COLLAZO, Carlos, E.; 35 Bergen Avenue, Ridgefield Park, NY 07660 (US). (74) Agents: SPIEGEL, Allen, J. et al.; Pfizer Inc., 235 East 42nd Street, New York, NY 10017 (US).		(81) Designated States: CA, DE (Utility model), JP, MX, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: ACETABULAR PLUG (57) Abstract <p>A plug is provided for use with a specially bored acetabular cup which thoroughly prevents debris (e.g. polymeric debris) from getting through any hole(s) in the cup and which is removable from the cup if desired. The plug is metal and acts with the hole in a compression fit relationship. A method for preventing debris from passing through a hole in an acetabular cup and into a patient's body is also given.</p> <div data-bbox="730 1050 1334 1785"> </div>		

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ACETABULAR PLUG**Background of the Invention**

This invention relates generally to implants for use in hip surgery and relates more particularly to an acetabular implant with specially designed plugs for plugging observation holes in that device or holes used for screw fixation or other purposes.

10 In acetabular cups for use in hip surgery, a hole or holes are sometimes present so as to enable the orthopedic surgeon to observe the placement of the acetabular cup in the patient's acetabulum so as to see whether the cup is properly seated in the acetabulum. If the surgeon has sufficient expertise so as to know whether or not the cup is properly seated without actually seeing the placement of the cup, such a hole
15 or holes in the acetabular cup may not be necessary.

Any such observation holes used in the acetabular cup for placement of the cup will necessarily have to be closed once the cup is finally positioned in the acetabulum in order to prevent debris from passing through the holes.

It is known to use screws or threaded plugs so as to close such observation
20 hole or holes in order to prevent debris from wear of the polymeric portion of the acetabular cup from getting through that observation hole and down into the patient's bone.

However, such threaded plugs have a definite disadvantage of exhibiting micromotion if not properly locked or torqued. Thus, debris can penetrate the
25 observation hole and come in contact with the patient's bone. Also, threaded plugs require a drive mechanism for insertion into the acetabular cup and are easily and often cross-threaded (i.e., the threads may be improperly aligned).

An object of this invention is a plug for use in closing an observation hole in an acetabular cup which does not exhibit micromotion and which thoroughly prevents
30 debris from getting through the hole and down into the patient's bone and which can also be removed from the acetabular cup.

Another object of this invention is a method for inserting an acetabular cup into a patient, such that the cup is properly seated within the patient's acetabulum and such that polymeric wear debris is prevented from coming into contact with the patient's
35 bone.

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Summary of the Invention

According to the invention, a plug which can be used in an acetabular implant, which prevents polymeric debris from coming into contact with a patient's bone, and which is also removable from the acetabular cup comprises: a hollow, threadless piece
5 of metal substantially in the shape of a cup having a side portion, a rim, and a bottom portion, and having a taper over at least a portion of the side portion so that the plug and a special two-part bore (i.e., counterbore) within the acetabular cup fit together in an interference fit. Preferably, a lip is present on the rim of the plug to facilitate removal of the plug, if desired.

10 Also, according to the invention, a kit for use in orthopedic hip surgery comprises such a metal plug (described above) and an acetabular cup with a special two-part bore (i.e., counterbore) located therein for placement of that acetabular cup within the patient's body such that the metal plug and the bore fit together in an interference fit, the plug cannot be pushed through the bore and the plug is extractable,
15 if desired, from the bore.

Further, according to the invention, a method for inserting an acetabular cup into a patient such that the cup is properly seated within the patient's acetabulum and such that polymeric wear debris is prevented from coming into contact with the patient's bone comprises: (a) inserting the acetabular cup of the kit of the invention (described
20 above) into the acetabulum of a patient, using the observation hole to properly seat the acetabular cup and (2) then inserting the metal plug of the kit of the invention into the observation hole so as to close the observation hole and so as to prevent debris from passing through the observation hole into the bone of the patient.

Brief Description of the Drawing

25 In Fig. 1, shown in cross-section is a preferred embodiment of a tapered metallic plug for use with a metallic acetabular cup having a two-part bore therewithin (not shown in Fig. 1), the plug being tapered along the entire length of the side portion.

In Fig. 1A, shown in cross-section is an alternative preferred embodiment of a metal plug for use with a metallic acetabular cup, the plug being tapered along only a
30 portion of the side portion of the plug.

In Fig. 2 is shown a cross-section of a preferred embodiment of an acetabular cup having a two-part bore located at the bottom of the hemispherical portion of the cup, that bore having a shoulder therewithin and to be used with the plug of Fig. 1.

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In Fig. 3 is shown a cross-sectional view of the acetabular cup of Fig. 2, together with the plug shown in Fig. 1 prior to the plug's being fully inserted into the bore of the acetabular cup.

In Fig. 4 is shown in cross-section the plug of Fig. 1 after it has been inserted
5 into the acetabular cup of Fig. 2 and is seated therewithin such that the bottom of the plug contacts the shoulder of the bore.

Detailed Description of the Drawing

Referring to the drawing, in Fig. 1 a preferred embodiment of the acetabular plug
10 of the invention is shown in cross-section. The plug 10 is made of metal and is itself substantially in the shape of a cup, and has a hollow portion 12, a substantially flat bottom portion 14, and a side portion 15 which has a taper 16 on at least a portion thereof. In the preferred embodiment shown in Fig. 1, the side portion 15 has a taper 18 along the entire side thereof.

In Fig. 1A, in another preferred embodiment the taper 18 extends only along a
15 portion of side portion 15 (sometimes referred to as a "leader"). The taper 18 is tapered at an angle α (alpha) with respect to a line which is perpendicular (or normal) to the substantially flat bottom portion 14 of the plug 10.

In Fig. 2, is shown a cross-sectional view of a preferred embodiment of an acetabular cup for use with the plug of the invention. The acetabular cup is referred
20 to generally as 24 and has a substantially hemispherical shape, has a hollowed out portion 26, in which the ball portion (not shown) of a hip implant will be free to rotate within a polyethylene shell (not shown) within the acetabular cup 24 when the cup 24 is positioned within a patient's acetabulum. The outer surface 28 of the acetabular cup 24 will contact the acetabulum bone of the patient when the acetabular cup 24 is
25 implanted within the patient's acetabulum. Ridges 29 in the cup 24 are present for holding a polyethylene insert (not shown) within the cup 24.

In order to properly seat the acetabular cup 24 within the acetabulum of the patient, a bore 30 will preferably be drilled through the outer surface 28 of acetabular cup 24. Preferably, bore 30 will be positioned such that the centerline 32 through bore
30 30 passes through the center 34 of the hemisphere which makes up acetabular cup 24.

Bore 30 has a total height H, 36, which is the sum of two parts, height h_1 , 38 plus height h_2 , 40. Bore 30 is made up of a first bore portion 42 and a second bore portion 44. First bore portion 42 has a diameter 46 and second bore portion has a

diameter 48, such that diameter 48 of second bore portion 44 is larger than diameter 46 of first bore portion 42. Hence, a shoulder 50 results. This shoulder 50 (also shown in Fig. 4) serves the function of preventing plug 10 from passing through bore 30 beyond shoulder 50.

- 5 In the practice of the invention, it is required that acetabular plug 10 have a taper 16 along at least a portion of side portion 15 so that an interference fit between side portion 15 and second bore portion 44 results.

Preferably, second bore portion 44 and first bore portion 42 will be formed as cylinders with straight sides having no taper for ease of manufacture of the bore (used
10 for visualizing placement of the acetabular cup 24).

If desired, side portion 15 of acetabular plug 10 can be tapered along only a portion thereof, that is, near the top edge 52 of side portion 15 which lies farthest from substantially flat bottom portion 14 of plug 10. Top edge 52 can extend inwardly to be a lip 53 (as shown in Fig. 3) for ease in removal of the plug 10 if removal is desired.

- 15 In Fig. 3, acetabular plug 10 is shown just prior to its being inserted into second bore portion 44 of bore 30. Corresponding parts are numbered correspondingly in Figs. 1, 1A, 2, 3, and 4.

In Fig. 4, acetabular plug 10 is shown seated within second bore portion 44 of bore 30, such that the progress of plug 10 is stopped by shoulder 50.

- 20 The plug 10 of the invention will be made of a biocompatible material, for example cobalt-chromium-molybdenum, stainless steel, or titanium.

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CLAIMS

1. An acetabular plug comprising a piece of metal substantially in the shape of a hollow cup with a bottom and a threadless side portion which is at least partially tapered.
- 5 2. A plug according to claim 1, wherein said plug has a top edge with an inwardly extending lip.
3. A plug according to claim 1 wherein said cup side portion is tapered along its entire length.
4. A plug according to claim 1, wherein said cup side portion is tapered
10 only along a portion of its length.
5. A kit comprising a metal plug and an acetabular cup prosthesis wherein
 - (a) said acetabular cup prosthesis has a first substantially cylindrical taperless, threadless bore and a second substantially cylindrical taperless, threadless bore therewithin, wherein said first bore and said second bore have unequal diameters
15 and are concentric, such that a shoulder is formed between said first bore and said second bore, and
 - (b) a plug comprising a piece of metal substantially in the shape of a hollow cup with a bottom, a threadless side portion, and a taper on at least a portion of said side portion,
20 wherein said plug and said second bore are shaped relative to each other such that an interference fit results between said metal plug and said second bore and wherein said shoulder prevents said metal plug from moving through said acetabular cup.
6. A kit according to claim 5 wherein said plug has a taper along the entire
25 length of said side portion.
7. A method for inserting an acetabular cup into a patient, such that the cup is properly seated within the patient's acetabulum and such that polymeric wear debris is prevented from coming into contact with the patient's bone, said method comprising:
 - (a) inserting the acetabular cup of the kit of claim 5 into the acetabulum of a patient,
30 using the observation hole to properly seat the acetabular cup and (2) then inserting the plug of the kit of claim 5 into the observation hole so as to close the observation hole and so as to prevent debris from passing through the observation hole into the bone of the patient.

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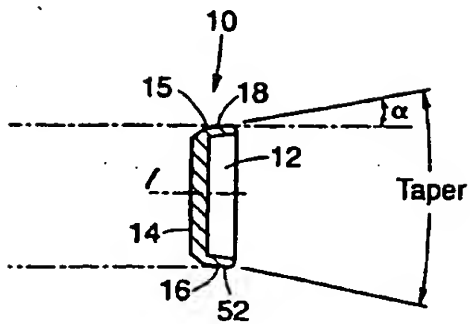
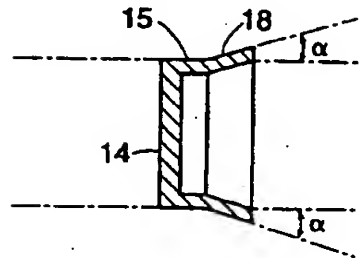
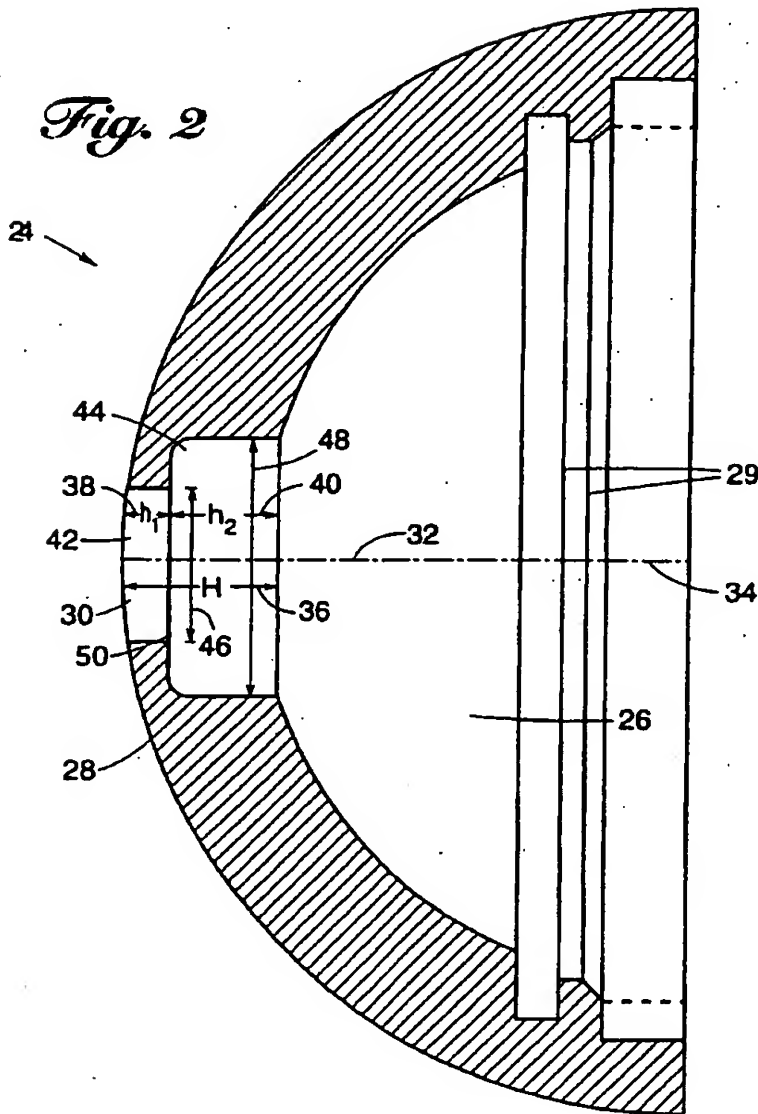
Fig. 1*Fig. 1A**Fig. 2*

Fig. 3

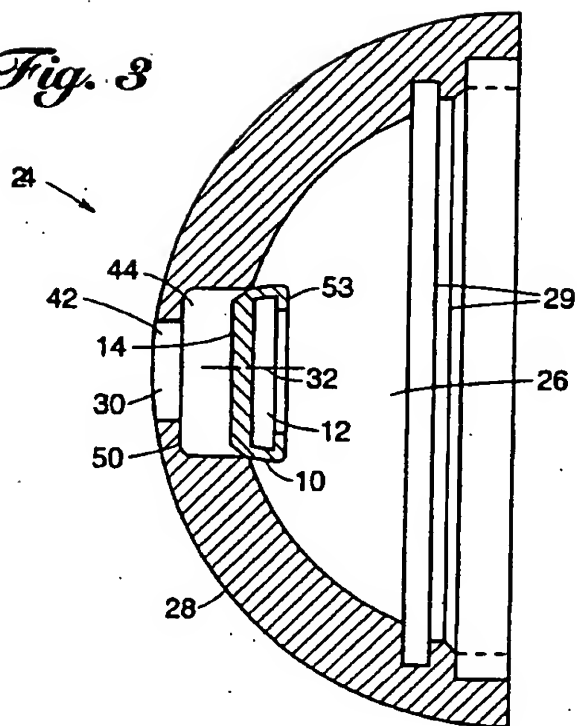
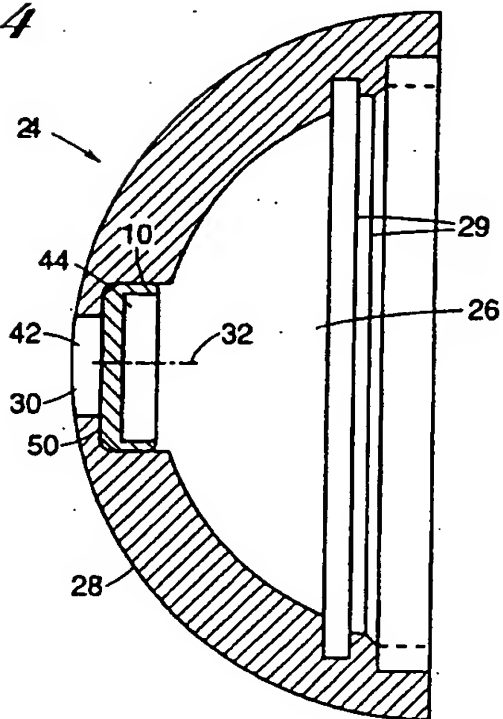


Fig. 4



INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/IB 95/01114

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/34 A61F2/30

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

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X	EP,A,0 244 720 (SULZER) 11 November 1987	1,3
Y	see page 6, line 5-14; figure 5	5,6
Y	US,A,4 955 325 (ZARNOWSKI) 11 September 1990 see abstract; figures	5,6
X	EP,A,0 444 381 (SULZER) 4 September 1991 see figure 2	1,3
X	US,A,4 180 873 (FIXEL) 1 January 1980 see the whole document	1-3
A	WO,A,94 05234 (SMITH & NEPHEW RICHARDS) 17 March 1994 see page 15, line 19-35; figure 18	1,5
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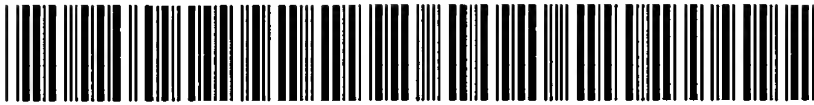
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P,A	EP,A,0 666 067 (SULZER) 9 August 1995 see the whole document -----	1



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